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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/082,920 | 02/25/2002 | Leonard Pinchuk | BSI-507US | 3520 |

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RATNERPRESTIA
P O BOX 980
VALLEY FORGE, PA 19482-0980

EXAMINER

PREBILIC, PAUL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3738 | |

DATE MAILED: 09/11/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|------------------|------------------|--|
| Application No. | PINCHUK, LEONARD | |
| Examiner | Art Unit | |
| Paul B. Prebilic | 3738 | |

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on February 25, 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities:

On page 1 of the specification, the continuing data is not updated with the current status of the parent application(s).

On page 6, line 28 to page 7, line 2, page 8, line 23 et seq. and page 9, line 5 et seq., Figures 19 and 20 are discussed at these locations but no such figures can be found in the drawings. Rather, there are 7 pages of drawings, numbered 1 to 7; the same number of pages listed in the transmittal filed February 25, 2002. For this reason, the specification and drawings do not match.

On page 9, line 5, "Figure 190" appears to be a typographical error.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4, the term "stent" has no clear antecedent basis and "suture material" lacks antecedent basis from claim 1.

In claim 6, the language "said plurality of sutures" lacks antecedent basis from claim 1.

In claim 7, line 3, the term "stent" lacks clear antecedent basis from claims 1 or 6, which uses the terminology "stent-graft."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choudhury (US 4,140,120) in view of Lenker et al (US 5,483,158). Choudhury discloses a method of using fluoroscopy or X-ray to determine the location and to make a diagnosis of an aneurysm (see column 2, lines 57-66). This step corresponds to the step of determining the length of the aneurysm as claimed. Particularly, the step of determining the length of the aneurysm is considered inherent to making a diagnosis thereof because such would be necessary to perform the surgery properly (i.e. to

perform an operable method). Next, the step of selecting and determining the length and size of the graft is inherent to Choudhury because this would be necessary to perform the surgery properly; see column 4, lines 1-4 and column 3, lines 24-38. The claimed deploying step is met by Choudhury where Choudhury uses X-ray and fluoroscopy to assure proper positioning of the graft; see column 3, line 18 to column 4, line 4. However, Choudhury fails to disclose a stent-graft with a dilation restriction means as claimed. However, Lenker teaches that stent grafts with dilation means were known as a means to repair aneurysms at the time the invention was made; see the abstract, Figure 5, and column 9, lines 10-35. Therefore, it is the Examiner's position that it would have been obvious to use the Lenker device in Choudhury's method for the same reasons that Lenker uses the same in their method of aneurysm repair; see Lenker on column 2, line 28 to column 3, line 27.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choudhury and Lenker et al as applied to claims 1-6 above, and further in view of Cox et al (US 5,824,040). Choudhury fails to teach cutting the graft as claimed. However, Cox et al teaches that it was known to cut similar grafts to the proper length prior to implantation at the time the invention was made; see column 12, lines 19-31. Hence, it is the Examiner's position that it would have been obvious to cut Choudhury's or Lenker's grafts to fit the implant site to make it properly fit the aneurysm and to avoid having the manufacturer a precise implant for the particular patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738